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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,683	04/11/2007	William J. Watkins	01692.315US2	4512
53684 7590 03/25/2008 VIKSNINS HARRIS & PADYS PLLP P.O BOX 111098 St. Paul, MN 55111-1098			EXAMINER MOORE, SUSANNA	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 03/25/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,683	Applicant(s) WATKINS, WILLIAM J.	
	Examiner SUSANNA MOORE	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55,57-65 and 71 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-55,57-65 and 71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The previous Restriction Requirement is vacated with this Supplemental Restriction Requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 4-55, 57, 58 and 71 are drawn to compounds of formula (I), wherein L1 and L2 are carbon and form a substituted pyrrolo[2,3-d]pyrimidine, compositions thereof and a process of making said compositions, classified in class 544, subclass 244, classified in class 514, subclass 265.1.
- II. Claims 1, 2, 4-55, 57, 58 and 71 are drawn to compounds of formula (I), wherein L1 is nitrogen and L2 is carbon and form a substituted purine, compositions thereof and a process of making said compositions, classified in class 544, subclass 262+, classified in class 514, subclass 263.1+.
- III. Claims 1-3, 5-55, 57, 58 and 71 are drawn to compounds of formula (I), wherein L1 is carbon and L2 is nitrogen and form a substituted pyrazolo[3,4-d]pyrimidine, compositions thereof and a process of making said compositions, classified in class 544, subclass 256, classified in class 514, subclass 262.1.
- IV. Claims 1, 57, 58 and 71 are drawn to compounds of formula (I), wherein L1 is nitrogen and L2 is nitrogen and form a substituted [1,2,3]triazolo[4,5-

d]pyrimidine, compositions thereof and a process of making said compositions, classified in class 544, subclass 254, classified in class 514, subclass 261.1.

- V. Claims 59-64 are drawn to a method of inhibiting a kinase with compounds of formula (I), wherein L1 is nitrogen and L2 is nitrogen and form a substituted pyrrolo[2,3-d]pyrimidine, classified in class 514, subclass 265.1.
- VI. Claims 59-64 are drawn to a method of inhibiting a kinase with compounds of formula (I), wherein L1 and L2 are carbon and form a substituted purine, classified in class 514, subclass 263.1+.
- VII. Claims 59-64 are drawn to a method of inhibiting a kinase with compounds of formula (I), wherein L1 is nitrogen and L2 is carbon and form a substituted pyrazolo[3,4-d]pyrimidine, classified in class 514, subclass 262.1.
- VIII. Claims 59-64 are drawn to a method of inhibiting a kinase with compounds of formula (I), wherein L1 is nitrogen and L2 is carbon and form a substituted [1,2,3]triazolo[4,5-d]pyrimidine, classified in class 514, subclass 261.1.
- IX. Claims 65 are drawn to a method of treating cancer with compounds of formula (I), wherein L1 and L2 are carbon and form a substituted pyrrolo[2,3-d]pyrimidine, classified in class 514, subclass 265.1.

- X. Claims 65 are drawn to a method of treating cancer with compounds of formula (I), wherein L1 is nitrogen and L2 is carbon and form a substituted purine, classified in class 514, subclass 263.1+.
- XI. Claims 65 are drawn to a method of treating cancer with compounds of formula (I), wherein L1 is nitrogen and L2 is nitrogen and form a substituted pyrazolo[3,4-d]pyrimidine, classified in class 514, subclass 262.1.
- XII. Claims 65 are drawn to a method of treating cancer with compounds of formula (I), wherein L1 is nitrogen and L2 is nitrogen and form a substituted [1,2,3]triazolo[4,5-d]pyrimidine, classified in class 514, subclass 261.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IV are independent and distinct from each other as they are drawn to compounds of the formula shown in claims 1 or 2, a composition and a method of making said compositions, wherein the compounds have divergent ring structures formed between L1 and L2. Group I provides pyrrolo[2,3-d]pyrimidine compounds where L1 and L2 are carbon. Group II forms purines where L1 is a nitrogen and L2 is carbon. Group III encompasses pyrazolo[3,4-d]pyrimidines, where L1 is carbon and L2 is nitrogen. Group IV embrace [1,2,3]triazolo[4,5-d]pyrimidine, wherein L1 is nitrogen and L2 is nitrogen. Each of groups I-IV are directed to

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compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of actions, different effects, and reactive conditions. It is noted that a reference disclosing a compound of one group would not necessarily disclose a compound of the other two groups. Additionally, the level of skill in the art is not such that one invention would be obvious over the other, i.e. they are patentable over each other. Chemical structures that are similar are presumed to function similarly, while chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Thus, by virtue of the different structures presented in groups I-IV, these inventions are distinct.

Inventions I-IV and V-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). The instant case claims a method of inhibiting JAK3, see claim 64, with the compounds of formula (I). JAK3 can be inhibited with compounds in the reference, US 20050187233 A1, which are benzopyrimidines, a bicyclic structure not disclosed in the instant Application.

Inventions I-IV and IX-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case cancer, which is claimed in claim 21, can be treated with an alkylating agent, e.g. altretamine, properties these compounds not disclosed to have.

Because these inventions are distinct for the reasons given above and the search required for group I is not required for group II-XII, restriction for examination purposes as indicated is proper. Groups I-XII are not identically classified under U.S. Patent Classification guidelines, thus, to search them together would present a search burden on the Examiner. Moreover, the searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together. Thus, groups I-XV have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rejoinder Advisory

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found

allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Susanna Moore/
Examiner, Art Unit 1624

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624